

| | | | |
|---|------------------------|-------------------|------------|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99) | Application Number | | 10595385 |
| | Filing Date | | 2006-04-13 |
| | First Named Inventor | Marcus A. Horwitz | |
| | Art Unit | | |
| | Examiner Name | | |
| | Attorney Docket Number | 51326-00019 | |

| U.S. PATENTS | | | | | | Remove |
|-------------------|---------|---------------|------------------------|------------|---|--|
| Examiner Initial* | Cite No | Patent Number | Kind Code ¹ | Issue Date | Name of Patentee or Applicant of cited Document | Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear |
| /MN/ | 1 | 5504005 | | 1996-04-02 | Bloom et al. | |
| /MN/ | 2 | 5583038 | | 1996-12-10 | Stover | |
| /MN/ | 3 | 5591632 | | 1997-01-07 | O'Donnell et al. | |
| /MN/ | 4 | 5679515 | | 1997-10-21 | Stover et al. | |
| /MN/ | 5 | 5700683 | | 1997-12-23 | Stover et al. | |
| /MN/ | 6 | 5736367 | | 1998-04-07 | Haun et al. | |
| /MN/ | 7 | 5776465 | | 1998-07-07 | O'Donnell et al. | |
| /MN/ | 8 | 5807723 | | 1998-09-15 | Aldovini et al. | |

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Not for submission under 37 CFR 1.99)

| | |
|------------------------|-------------------|
| Application Number | 10595385 |
| Filing Date | 2006-04-13 |
| First Named Inventor | Marcus A. Horwitz |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 51326-00019 |

| | | | | | | |
|------|----|---------|----|------------|-----------------|--|
| /MN/ | 9 | 5830475 | | 1998-11-03 | Aldovini et al. | |
| /MN/ | 10 | 5854055 | | 1998-12-29 | Bloom et al. | |
| /MN/ | 11 | 5866403 | | 1999-02-02 | Aldovini et al. | |
| /MN/ | 12 | 5869057 | | 1999-02-09 | Rock | |
| /MN/ | 13 | 6015696 | | 2000-01-18 | Yamada et al. | |
| /MN/ | 14 | 6471967 | B1 | 2002-10-29 | Horwitz et al. | |

If you wish to add additional U.S. Patent citation information please click the Add button.

Add

U.S.PATENT APPLICATION PUBLICATIONS

Remove

| Examiner Initial* | Cite No | Publication Number | Kind Code ¹ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear |
|-------------------|---------|--------------------|------------------------|------------------|---|--|
| | 1 | | | | | |

If you wish to add additional U.S. Published Application citation information please click the Add button.

Add

FOREIGN PATENT DOCUMENTS

Remove

| Examiner Initial* | Cite No | Foreign Document Number ³ | Country Code ² i | Kind Code ⁴ | Publication Date | Name of Patentee or Applicant of cited Document | Pages,Columns,Lines where Relevant Passages or Relevant Figures Appear | T ⁵ |
|-------------------|---------|--------------------------------------|-----------------------------|------------------------|------------------|---|--|----------------|
|-------------------|---------|--------------------------------------|-----------------------------|------------------------|------------------|---|--|----------------|

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

| | |
|------------------------|-------------------|
| Application Number | 10595385 |
| Filing Date | 2006-04-13 |
| First Named Inventor | Marcus A. Horwitz |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 51326-00019 |

| | | | | | | | | |
|------|---|-------------|----|--|------------|---|--|--------------------------|
| /MN/ | 1 | 2004/031356 | WO | | 2004-04-15 | The Regents of the University of California | | <input type="checkbox"/> |
| /MN/ | 2 | 88/06626 | WO | | 1988-09-07 | Whitehead Institute for Biomedical Research | | <input type="checkbox"/> |

If you wish to add additional Foreign Patent Document citation information please click the Add button [Add](#)

NON-PATENT LITERATURE DOCUMENTS

[Remove](#)

| Examiner Initials* | Cite No | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, pages(s), volume-issue number(s), publisher, city and/or country where published. | T ⁵ |
|--------------------|---------|---|--------------------------|
| /MN/ | 1 | CIRILLO et al., "Bacterial Vaccine Vectors and Bacillus Calmette-Guerin", Clinical Infectious Diseases, 20:1001-9 (1995) | <input type="checkbox"/> |
| /MN/ | 2 | FUERST et al., "Development and Analysis of Recombinant BCG Vector Systems", AIDS Research and Human Retroviruses, 8:1451-5 (1992) | <input type="checkbox"/> |
| /MN/ | 3 | HANSON et al., "Efficacy and Safety of Live Recombinant BCG Vaccines", Dev. Biol. Stand., 84:229-36 (1995) | <input type="checkbox"/> |
| /MN/ | 4 | HARTH et al., "High-Level Heterologous Expression and Secretion in Rapidly Growing Nonpathogenic Mycobacteria of Four Major Mycobacterium Tuberculosis Extracellular Proteins Considered to be Leading Vaccine Candidates and Drug Targets", Infection and Immunity, 65:2321-8 (1997) | <input type="checkbox"/> |
| /MN/ | 5 | HARTH et al., "Novel Insights into the Genetics, Biochemistry, and Immunocytochemistry of the 30-Kilodalton Major Extracellular Protein of Mycobacterium Tuberculosis", Infection and Immunity, 64:3038-47 (1996) | <input type="checkbox"/> |
| /MN/ | 6 | HORWTIZ et al., "Recombinant Bacillus Calmette-Guerin (BCG) Vaccines Expressing the Mycobacterium Tuberculosis 30-kDa Major Secretory Protein Induce Greater Protective Immunity Against Tuberculosis Than Conventional BCG Vaccines in a Highly Susceptible Animal Model", PNAS, 97:13853-8 (2000) | <input type="checkbox"/> |
| /MN/ | 7 | LANGERMANN et al., "Protective Humoral Response Against Pneumococcal Infection in Mice Elicited by Recombinant Bacille Calmette-Guerin Vaccines Expressing Pneumococcal Surface Protein A", J Exp Med., 180:2277-86 (1994) | <input type="checkbox"/> |

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

| | |
|------------------------|-------------------|
| Application Number | 10595385 |
| Filing Date | 2006-04-13 |
| First Named Inventor | Marcus A. Horwitz |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 51326-00019 |

| | | | |
|------|----|--|--------------------------|
| /MN/ | 8 | LANGERMANN et al., "Systemic and Mucosal Immunity Induced by BCG Vector Expressing Outer-Surface Protein A of Borrelia Burgdorferi", Nature, 372:552-5 (1994) | <input type="checkbox"/> |
| /MN/ | 9 | LEE et al., "T-Cell Epitope Mapping of the Three Most Abundant Extracellular Proteins of Mycobacterium Tuberculosis in Outbred Guinea Pigs", Infection and Immunity, 67:2665-70 (1999) | <input type="checkbox"/> |
| /MN/ | 10 | NAITO et al., "The Antigen 85 Complex Vaccine Against Experimental Mycobacterium Lepae Infection in Mice", Vaccine, 19:795-8 (2000) | <input type="checkbox"/> |
| /MN/ | 11 | OHARA et al., "Characterization of the Transcriptional Initiation Regions of Genes for the Major Secreted Protein Antigens 85C and MPB51 of Mycobacterium Bovis BCG", Microbial Pathogenesis, 23:303-10, (1997) | <input type="checkbox"/> |
| /MN/ | 12 | OHARA et al., "Inhibition of Multiplication of Mycobacterium Lepae in Mouse Foot Pads by Recombinant Bacillus Calmette-Guerin (BCG)", Vaccine, 19:1294-7 (2000) | <input type="checkbox"/> |
| /MN/ | 13 | STOVER et al., "New Use of BCG for Recombinant Vaccines", Nature, 351:456-60 (1991) | <input type="checkbox"/> |
| /MN/ | 14 | STOVER et al., "Protective Immunity Elicited by rBCG Vaccines", Dev. Biol. Stand., 82:163-70 (1994) | <input type="checkbox"/> |
| /MN/ | 15 | STOVER et al., "Protective Immunity Elicited by Recombinant Bacille Calmette-Guerin (BCG) Expressing Outer Surface Protein A (OspA) Lipoprotein: A Candidate Lyme Disease Vaccine", J. Exp. Med., 178:197-209 (1993) | <input type="checkbox"/> |
| /MN/ | 16 | STOVER et al., "Use of Recombinant BCG as a Vaccine Delivery Vehicle", Advances in Experimental Medicine and Biology, 327: 175-82 (1992) | <input type="checkbox"/> |
| /MN/ | 17 | YASUTOMI et al., "Immunization with Recombinant BCG-SIV Elicits SIV-Specific Cytotoxic T. Lymphocytes in Rhesus Monkeys", The Journal of Immunology, 150:3101-7 (1993) | <input type="checkbox"/> |

If you wish to add additional non-patent literature document citation information please click the Add button

Add

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

| | |
|------------------------|-------------------|
| Application Number | 10595385 |
| Filing Date | 2006-04-13 |
| First Named Inventor | Marcus A. Horwitz |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 51326-00019 |

EXAMINER SIGNATURE

| | | | |
|--------------------|--------------------|-----------------|------------|
| Examiner Signature | /Albert M Navarro/ | Date Considered | 08/06/2008 |
|--------------------|--------------------|-----------------|------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through a citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ See Kind Codes of USPTO Patent Documents at www.USPTO.GOV or MPEP 901.04. ² Enter office that issued the document, by the two-letter code (WIPO Standard ST.3). ³ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁴ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁵ Applicant is to place a check mark here if English language translation is attached.

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**
(Not for submission under 37 CFR 1.99)

| | |
|------------------------|-------------------|
| Application Number | 10595385 |
| Filing Date | 2006-04-13 |
| First Named Inventor | Marcus A. Horwitz |
| Art Unit | |
| Examiner Name | |
| Attorney Docket Number | 51326-00019 |

CERTIFICATION STATEMENT

Please see 37 CFR 1.97 and 1.98 to make the appropriate selection(s):

☐ That each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(1).

OR

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement. See 37 CFR 1.97(e)(2).

☒ See attached certification statement.

☐ Fee set forth in 37 CFR 1.17 (p) has been submitted herewith.

☐ None

SIGNATURE

A signature of the applicant or representative is required in accordance with CFR 1.33, 10.18. Please see CFR 1.4(d) for the form of the signature.

| | | | |
|------------|---------------------------|---------------------|------------|
| Signature | /Michelle S. Glasky/ | Date (YYYY-MM-DD) | 2006-07-17 |
| Name/Print | Michelle S. Glasky, Ph.D. | Registration Number | 54124 |

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 hour to complete, including gathering, preparing and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C. 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether the Freedom of Information Act requires disclosure of these records.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspections or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.